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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DIANNE S. METZGER,
IAN R. VAUGHAN, and CALIE B. GREY

Appeal 2017-009216[1]
Application 14/173,280
Technology Center 3700

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and MICHAEL J. FITZPATRICK, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims to devices for augmenting a tibial stem for a human knee. The Examiner rejected the claims under 35 U.S.C. § 102 as anticipated and under 35 U.S.C. § 103 as obvious. Pursuant to 35 U.S.C § 134, Appellants appeal the Examiner's determination that the claims are unpatentable. We have jurisdiction under 35 U.S.C. § 6(b). The rejections are affirmed-in-part. A new ground of rejection pursuant 37 C.F.R. § 41.50(b) is set forth under 35 U.S.C. § 103.

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[1] The Appeal Brief ("Br.") (Feb. 1, 2017), page 1, identifies Zimmer, Inc., as the real-party-in-interest.

STATEMENT OF THE CASE

Claims 1–6, 8–15, and 17–24 stand finally rejected by the Examiner as follows:

1. Claims 1 and 11 under pre-AIA 35 U.S.C. § 102(a) as anticipated by Phlipot (US Pat. 5,344,461, issued Sept. 6, 1994). Ans. 2.

2. Claims 17, 18, 20, 21, 23, and 24 under pre-AIA 35 U.S.C. § 102(a) as anticipated by Zubok (US Pat. Appl. Publ. 2012/0310361 A1, published Dec. 6, 2012). Ans. 3.

3. Claims 1–6, 8–10, 12–15, 19, and 22 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Zubok. Ans. 4.

Independent claim 1 is illustrative and reads as follows:

> 1. A device for augmenting a tibial stem for a human knee, the tibial stem coupled to a distal side of a tibial platform, a proximal side of the tibial platform couplable to a surface for articulation with a femoral component, the device comprising:
>
> a tibial augment configured to couple to the tibial platform proximate a distal side of the tibial platform, the tibial augment including a medial side, having a medial taper on at least a portion of its periphery extending continuously from a proximal side of the tibial augment to a distal side of the tibial augment, and a lateral side, having a lateral taper on at least a portion of its periphery extending continuously from the proximal side of the tibial augment to the distal side of the tibial augment;
>
> wherein at least a portion of the medial taper is different from at least a portion of the lateral taper.

ANTICIPATION BY PHLIPOT

Claim 1

Claim 1 is directed to a device for augmenting a tibial stem for a human knee. The device is utilized in knee repair and replacement surgery.

Spec. 2:7–24. During knee surgery, a proximal end of the tibia is cut to a particular size or shape, and then the tibial stem is attached to the proximal end of the tibia. *Id.* at 1:29–31; 2:10–11. The stem is coupled to a tibia platform which is attached to the proximal end of the tibia using a tibial augment. The claim requires that the device comprise "a tibial augment configured to couple to the tibial platform proximate a distal side of the tibial platform." The Specification explains that the augment

> can reduce or eliminate a lateral overhang of the tibial platform with respect to the cut proximal end of the tibia. The tibial augment may have a tapered periphery. The taper may extend inward in a distal direction. The taper may vary along the periphery of the tibial augment, so that at least a portion of a medial taper is different from at least a portion of a lateral taper. Such a taper that varies along the periphery of the tibial augment may help reduce or eliminate the lateral overhang of the tibial platform with respect to the cut proximal end of the tibia, and may do so better than a taper that does not vary along the periphery of the tibial augment.

Id. at 2:12–20.

In accordance with the Specification's explanation, the claimed tibial augment has medial and lateral tapers "on at least a portion of its periphery," where "at least a portion of the medial taper is different from at least a portion of the lateral taper."

For illustrative purposes, Figure 1 of the Specification is reproduced below showing the platform and tibial augment (shading of the augment has been added for clarity):

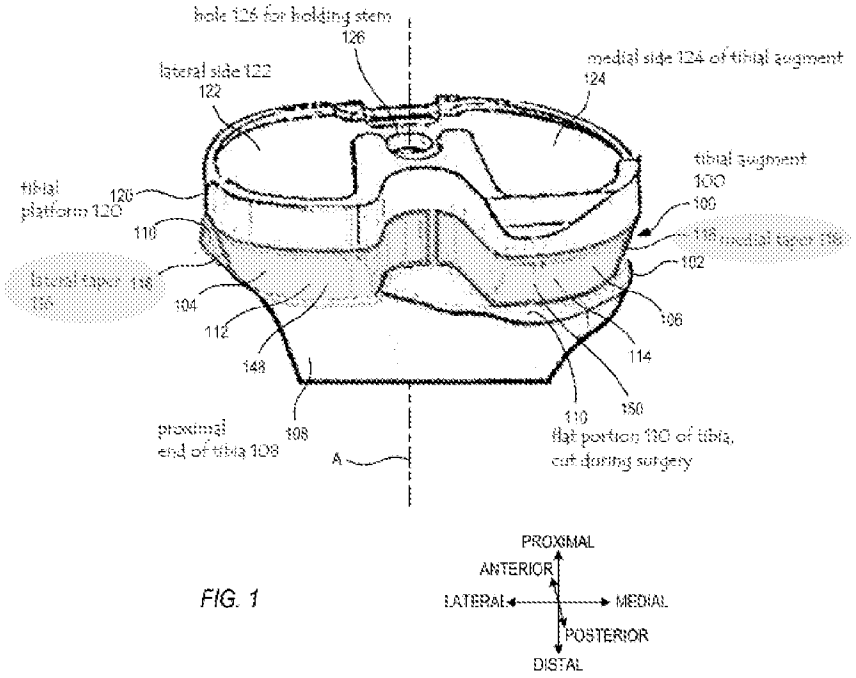

FIG. 1

Figure 1 shows the tibial platform 120 having a hole 126 for the tibial stem, the tibial augment 100 coupled to the tibial platform 120, and the tibial augment 100 lying against the flat portion 110 of the proximal end of the tibia 108. The figure shows the lateral and medial tapers 116 and 118, respectively. 148 and 150 are the lateral posterior taper and medial posterior taper, respectively. Spec. 9:13–19.

Rejection

The Examiner rejected claims 1 and 11 as anticipated by Phlipot. Ans. 2. The Examiner found that Phlipot describes a device comprising the same elements as recited in the claim, including a tibial stem, tibial platform ("tibial tray" in Phlipot), and tibial augment. Final Act. 8. The Examiner further found that Phlipot teaches that the augment has lateral and medial tapers as required by claim 1 and that the tapers are different. *Id.* The Examiner identified Figures 6 and 8, and column 2, lines 50–60 of Phlipot as

evidence that the tibial augment meets the taper limitations of claim 1. *Id.* at 3–4 and 8.

Figure 6 of Phlipot, with the Examiner's annotations, is reproduced below:

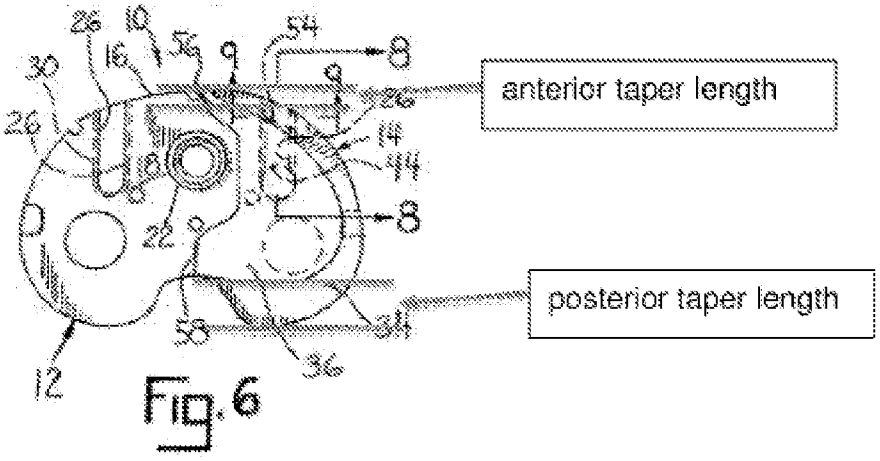

Figure 6 of Phlipot shows tibial augment 14. Phlipot teaches:

> Modular augmentation blocks **14**, only one shown, are shaped having an outer periphery **34** which is angled from the proximal surface **36** toward the distal surface **38** such that the edge of the proximal surface **40** of the outer periphery of the block **14** is in alignment with the edge of the distal surface **18** of the tibial tray **16**. The outer periphery **34** follows the periphery of approximately one half of the tibial tray **16** as illustrated in FIG. **6**.

Phlipot 2:51–59 (underlining added for emphasis). The "tibial tray 16" corresponds to the claimed tibial platform. Thus, as found by the Examiner, Phlipot shows an augment having tapers as required by the claim.

Figure 6 of Phlipot only shows one augment on the medial side. The claims, however, require both medial and lateral augments, each having tapers. However, Phlipot teaches that the use of augmentation blocks is

known to one of ordinary skill in the art. Phlipot 2:23–25. Phlipot teaches that only one augmentation block is shown in Figure 6 for illustrative purposes, but in practice, "a set of augmentation blocks would be provided to the surgeon each having a different thickness and angular orientation" and that, with the set, "the surgeon may build the optimum implant provisional for the patient." *Id.* at 2:18–23. Thus, while only a medial tibial augment is shown in Figure 6, a lateral augment would also be present to ensure that the platform tray is placed evenly on the surface of the resected tibia.

The Examiner found that, in use when both lateral and medial augments are present, the "anterior portion of the medial taper can be considered the taper portion of the medial portion," that the "posterior portion of the lateral taper can be considered the tapered portion of the lateral portion," and that "[w]hen compared, the taper of these portions will differ." Final Act. 3–4; Ans. 3. The Examiner also explained why the tapers are angled differently ("in order to achieve the same height change over differing lengths, the taper must be at different angles at the anterior vs. posterior portions"). Final Act. 3.

Discussion

Appellants contend that Phlipot "does not disclose, teach, or even suggest *'wherein at least a portion of the medial taper is different from at least a portion of the lateral taper',* as recited by independent claim 1." Br. 6. Appellants acknowledge the Examiner's annotation of Figure 6 of Phlipot, but argue that it does not provide a teaching as to medial and lateral tapers, and that "***only one*** of the ***medial*** or ***lateral*** sides of the tibial tray **16**

has a taper; the other of the medial or lateral sides lacks such a taper." *Id.* at 7.

Appellants' argument does not persuade us that the Examiner erred.

Appellants refer to the tibial tray **16** as having a taper (above), but the taper required by the claim and referenced by the Examiner is the taper of the tibial augment **14**. We, therefore, understand Appellants' reference to the taper of the tibial tray to be an error, and for Appellants to have intended to refer to the tibial augment's taper because that is the only taper described in Phlipot and required by the claims.

With regard to the taper of the augment, Appellants state that only one of the sides has a taper. Br. 7 (see passage reproduced above).

We do not agree. As explained in Phlipot, although only one augment **14** is shown in Figure 6, Phlipot teaches that this is for illustrative purposes and that in practice, "a set of augmentation blocks would be provided to the surgeon each having a different thickness and angular orientation" and that with the set, "the surgeon may build the optimum implant provisional for the patient." Phlipot 2:18–23. Thus, while an augment **14** is shown on the right side of the tibial tray **16** of Figure 6, "in use" (Ans. 3), there would also be an augment on the left side to make sure the tray is set evenly against the resected bone.

To illustrate the anterior, posterior, lateral, and medial anatomical positions, Figure 2 of the Specification is reproduced below with labels added by annotation to show the tapers:

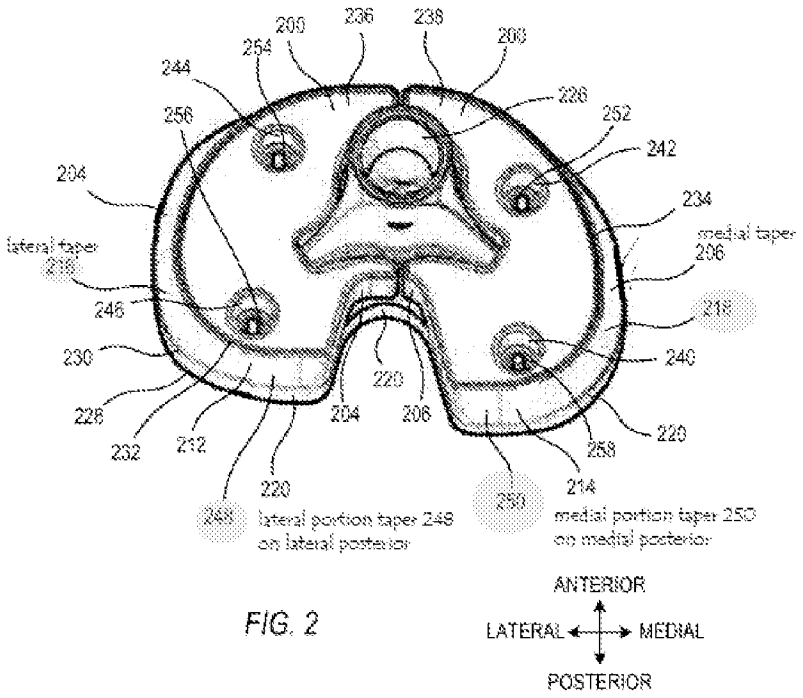

FIG. 2

As shown in Figure 2 of the Specification, 216 is the lateral taper because it is on the lateral side of the augment, namely facing away from the midline of the body. 206 is the medial taper because it is on the medial side of taper, namely facing toward the midline of the body. "The lateral posterior portion 212 includes a lateral portion taper 248 on at least a portion of its periphery." Spec. 10:3–4. "The medial posterior portion 214 includes a medial portion taper 250 on at least a portion of its periphery." *Id.* at 10:9–10. Figure 2 of the Specification looks similar to Figure 6 of Phlipot, which is reproduced above.

For the reasons described above, Phlipot's device necessarily has both lateral and medial augment blocks (Phlipot 2:18–23). The anterior and posterior portions are shown in Fig. 6 (*supra* 5) of Phlipot as having different tapers and as explained in Phlipot's description ("angular orientation"; "angled" (Phlipot 2:20–22; 2:51–56)).

The medial anterior taper in Figure 6 of Phlipot (shown) is different from the lateral posterior taper of Figure 6 of Phlipot (not shown) because the anterior and posterior tapers are different (*see* the Examiner's annotations to Fig. 6 of Phlipot at page 5 *supra*.) and there is an augment on both lateral and medial sides of the tibial tray 16. Thus, Phlipot meets the claim limitation of "wherein at least a portion of the medial taper is different from at least a portion of the lateral taper." Appellants deny this feature is described by Phlipot, but did not adequately identify a flaw in the Examiner's findings which are supported by a preponderance of the evidence described above.

Accordingly, the rejection of claim 1 as anticipated by Phlipot is affirmed. Dependent claim 11 was not argued separately and therefore falls with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

ANTICIPATION REJECTION BY ZUBOK

The Examiner rejected claims 17, 18, 20, 21, 23, and 24 as anticipated by Zubok.

Independent claim 17 is directed to a device for augmenting a tibial component for a human knee. The device comprises a tibial augment having medial and lateral tapers, where "the lateral side of the tibial augment including a lateral posterior portion having a lateral posterior taper on at least a portion of its periphery." The claim also requires that "at least a portion of the lateral posterior taper is different from at least one other portion of the lateral taper."

Independent claim 21 is directed to a system of augmenting a tibial stem for a human knee. The system comprises a plurality of augments

having different lateral sizes. Each augment has a lateral and medial side having tapers, where at least one augment "includes a medial taper portion that is different from a lateral taper portion."[2]

The Examiner identified Figures 2A–2D of Zubok as describing a tibial augment. Final Act. 6. The Examiner found that the augment has tapered portions as shown in the figures and described in paragraph 98 of Zubok. *Id.* The Examiner found that this disclosure describes that the lateral portions are different as required by claim 17. *Id.* The Examiner made similar findings with respect to clam 21. *Id.* at 7.

Fig. 2A of Zubok is reproduced below:

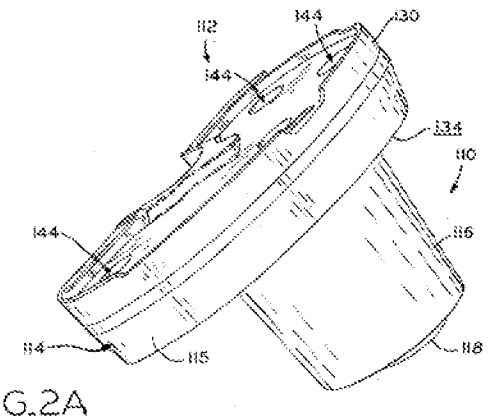

FIG.2A

Fig. 2D shows platform 114 with tapered portion 115. Zubok ¶ 98.

Appellants contend "that Zubok does not indicate that a taper varies at any point around a periphery" and thus does not meet the requirements of claims 17 and 21 of an augment having different tapers along its periphery. Br. 8. Appellants contend that paragraph 98 of Zubok teaches that platform **114** can have one side with a smaller size, "e.g., a smaller ***width*** and a

[2] It is not clear from the rejections why the Examiner did not include claim 21 in the rejection based on Phlipot.

smaller ***length***," than the other side. *Id.* at 9. Appellants argue that, for example, "the platform **114** can taper from the anterior side to the posterior side, in order to accommodate the different anterior and posterior ***sizes,*** but the cited portions of Zubok do not appear to disclose how the ***taper*** is configured." *Id.* Appellants provide an annotated drawing of Zubok's Fig. 2E which is said to show the *same* taper along the periphery of the platform. *Id.* at 10.

The issue in dispute between the Examiner and Appellants is whether Zubok teaches a varying taper of the augment as required by both claims 17 and 21, rather than a variance in just its width and size as asserted by Appellants.

Paragraph 98 of Zubok teaches:

> For example, referring to FIG. 2A, platform **114** includes tapered portion **115**, which may taper in overall width and anteroposterior length in a similar fashion to a natural proximal tibia. Tapered portion **115** is beneficial when a large amount of the natural proximal tibia is resected, thereby requiring a large thickness T_L of platform **114** to maintain the natural joint line of the knee (as discussed above).

Zubok ¶ 98.

Paragraph 98 states that the tapered portion of the platform "may taper in overall width and anteroposterior length in a similar fashion to a natural proximal tibia." The Examiner found that this teaching established a variance in the taper along the periphery to match the natural taper of the bone extending down the vertical axis. Ans. 9. In other words, the Examiner appears to have read "width" and "length" to mean that the angle of the taper differed along its periphery.

However, as discussed by Appellants, Fig. 2A does not show a difference in the *angle* of the taper. The Examiner did not adequately explain why changing the width and length of the augment would necessarily mean the angle of the taper is also changed to match the taper of the bone. For example, Fig. 4A of Zubok shows a varying width of the platform 314 (tibial augment), but the taper is not shown as different along the periphery. Zubok ¶ 104. The Examiner pointed to the natural taper of the tibia (Ans. 4), but Zubok does not explicitly teach that the platform's taper matches the natural taper of the tibia, rather it teaches the taper is beneficial for thickness reasons to maintain the natural joint line. Zubok ¶ 98 (reproduced above). The Examiner also did not establish that a "taper in overall width and anteroposterior length in a similar fashion to a natural proximal tibia" necessarily means that the angle of the taper in the inward or outward direction is necessarily changing, rather than the width of the augment.

Thus, while Zubok shows a taper, we are compelled to agree with Appellants that Zubok does not describe how the taper is configured along its periphery and the Examiner did not adequately explain why the augment must necessarily have both a medial and lateral taper as required by claim 17, where the lateral taper is different in different portions. The Examiner also did not adequately explain why the augment must necessarily have both a medial and lateral taper as required by claim 21, where the medial and lateral taper is different in different portions.

Anticipation "may not be established by probabilities or possibilities." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (internal citation and quotation marks omitted). The Examiner did not explain why the claimed

configurations of claims 17 and 21 are necessarily described by Zubok in the manner required by 35 U.S.C. 102. Consequently, the rejection of claims 17 and 21, and dependent claims 18, 20, 23, and 24, as anticipated by Zubok is reversed.

OBVIOUSNESS BASED ON ZUBOK

Claims 1–6, 8–10, 12–15, 19, and 22 are rejected as obvious in view of Zubok.

As explained in paragraphs 14, 15, and 77, Zubok teaches that the platform **114** is installed on the resected tibia to match its shape, with the medullary portion inserted into the tibia. Zubok teaches:

> In one form thereof, the present disclosure provides a support structure for use in conjunction with a prosthesis component, the support structure comprising: a platform having a proximal surface and a distal surface defining a platform thickness therebetween, the proximal surface and the distal surface cooperating to define a platform outer periphery shaped to correspond with a periphery of a resected proximal tibia, the platform outer periphery defining a platform medial-lateral width and a platform anteroposterior length.

Zubok ¶ 14 (emphasis added).

Because Zubok teaches that the platform has an "outer periphery shaped to correspond with a periphery of a resected proximal tibia," it would have been obvious to make different portions of the platform have different tapers to match the varying taper of the natural tibia. Ans. 9–10.

With respect to the limitation of claim 1 that the taper is "extending continuously," the Examiner found

> Where the only difference between the prior art and the claims is a recitation of the size and shape of the claimed device and

> the device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device (MPEP 2144.4). Applicant does not disclose why it is critical for the medial and lateral peripheries tapering continuously from the proximal to distal sides of the implant. Therefore, it would be obvious to one of ordinary skill in the art, prior to the time of the invention, to modify Zubok's device to have the taper extend from the proximal to distal side for situations where a shorter augment is needed due to a thicker tibial tray or lesser resection of the bone, thus obviating the need for the non-tapered portion of the device.

Final Act. 10–11.

Appellants contend that the Examiner erred in stating the Specification lacks a statement of the advantage of having a continuous taper. Br. 13. Appellants cite the following disclosure in the Specification:

> The present inventors have found that having a taper that varies along its periphery may be further advantageous. Such a varying taper may more closely follow the footprint of the bone at the proximal end of the tibia 108, and may desirably reduce the amount of exposed bone or overhang over the edge of the bone.

Spec. 8:19–22.

However, as indicated above, Zubok teaches "a platform outer periphery shaped to correspond with a periphery of a resected proximal tibia" (Zubok ¶ 14), making it obvious to vary the taper to match the natural taper of the bone. Thus, the Examiner's determination that claim 1 would have been obvious to one of ordinary skill in the art based on Zubok is supported by a preponderance of the evidence. Accordingly, the obviousness rejection of claim 1 in view of Zubok is affirmed. Claims 2–6, 8–10, 12–15, 19, and 22 were not argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

NEW GROUND OF REJECTION BASED ON ZUBOK

Claim 17

The Examiner did not include claim 17 in the obviousness rejection based on Zubok. Claim 17 recites that "wherein at least a portion of the lateral posterior taper is different from at least one other portion of the lateral taper." Based on Zubok's teachings ("outer periphery shaped to correspond with a periphery of a resected proximal tibia"), we find that it would have been obvious to one of ordinary skill in the art to vary the taper along the periphery to match the natural taper of the tibial bone to produce an augment where the lateral posterior taper is different from at least one other lateral portion taper. *See* Zubok ¶¶ 14, 15, 16, 77. This is a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

With respect to claims 18, 20, 21, 23, and 24, which we found not to be anticipated by Zubok, we leave to the Examiner to determine whether such claims would have been obvious based on Zubok.

SUMMARY

1. The rejection of claims 1 and 11 as anticipated by Phlipot is affirmed.

2. The rejection of claims 17, 18, 20, 21, 23, and 24 as anticipated by Zubok is reversed.

3. The rejection of claims 1–6, 8–10, 12–15, 19, and 22 as obvious in view of Zubok is affirmed.

4. A new ground of rejection of claim 17 is set forth pursuant to 37 C.F.R. § 41.50(b) under 35 U.S.C. § 103(a) as obvious in view of Zubok.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

> When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:
>
> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing.* Request that the proceeding be reheard under §41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the MPEP § 1214.01.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). *See* 37 C.F.R. §§ 41.50(f), 41.52(b).

AFFIRMED-IN-PART; 37 C.F.R. § 41.50(b)